

*REMARKS/ARGUMENTS**The Invention*

The invention is directed to a method of inhibiting metastasis of a tumor cell in a mammal. The tumor cell expresses CXC Chemokine Receptor-4 (CXCR4) and the method comprises administering to the mammal a polypeptide of SEQ ID NO: 1 or a CXCR4 antagonist that is not an antibody that binds CXCR4 in an amount sufficient to inhibit metastasis of the tumor cell. The invention also is directed to a method of inhibiting growth of a tumor cell comprising administering to the tumor cell a polypeptide of SEQ ID NO: 1.

The Pending Claims

Claims 1-11 and 36-39 are currently pending. Claims 1-11 are directed to the method of inhibiting metastasis of a tumor cell, and claims 36-39 are directed to the method of inhibiting growth of a tumor cell.

The Amendments to the Claims

Claims 12-35 have been cancelled as being drawn to a nonelected invention in response to a restriction requirement. Applicants reserve the right to pursue any cancelled subject matter in a continuation, continuation-in-part, divisional, or other application. Cancellation of any subject matter should not be construed as abandonment of that subject matter. Accordingly, no new matter has been added by way of the amendments to the claims.

The Office Action

Claims 1-11 and 36-39 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Koshiba et al., *Clinical Cancer Research*, 6, 3530-35 (2000) ("Koshiba") alone or in combination with WO 99/50461 (Murphy et al.) ("the Murphy PCT application") and WO 99/47158 (Clark-Lewis) ("the Clark-Lewis PCT application"). Reconsideration of these rejections is respectfully requested.

Discussion of Rejections Under 35 § U.S.C. 103

Claims 1-11 and 36-39 have been rejected under Section 103 as allegedly obvious over Koshiba alone or in combination with the Murphy PCT application and the Clark-Lewis PCT application. Applicants traverse the rejection.

The Office Action alleges that Koshiba teaches or suggests the use of the T22 polypeptide to inhibit metastasis. Contrary to the allegations of the Office Action, however, Koshiba discloses only *in vitro* testing of T22 and expressly states that the *in vivo* role of the T22 polypeptide with respect to metastasis (*i.e.*, tumor spread) is unknown:

The mode of action of chemokines depends heavily on the local environment....In this situation, *in vitro* migration assays may not predict *in vivo* function.

(Koshiba at p. 3535, col. 1, lines 11-15). Koshiba goes on to state that additional *in vivo* testing is required to determine whether or not T22 suppresses tumor spread and to clarify its role in pancreatic cancer (Koshiba at p. 3535, col. 1, lines 23-27).

Accordingly, Koshiba would not have provided, at the time of the invention, a reasonable expectation that T22 could be used to inhibit metastasis, as required to establish *prima facie* obviousness. An invitation to experiment or “obvious to try” rationale is not enough. *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

Furthermore, neither Koshiba nor any other evidence cited in the Office Action provides any guidance as to the type of testing that would be required or the parameters that should be varied in order to arrive at a method of using T22 to inhibit metastasis. Indeed, such guidance is found only in the Applicants’ own disclosure, which cannot be used as prior art to the claims.

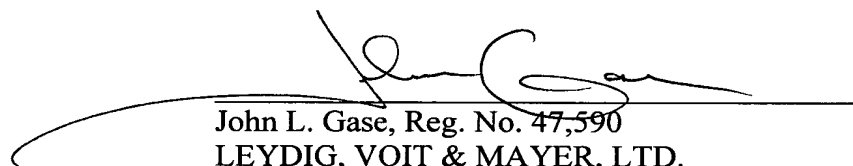
The Office Action relies on the Murphy PCT application for its alleged disclosure of modulating CXCR4 activity to inhibit growth of tumors in organs other than the pancreas (*e.g.*, liver and skin). Also, the Office Action relies on the Clark-Lewis PCT application for its alleged disclosure of a variety of therapeutic uses and effective dosages of CXCR4 antagonists. However, neither the Murphy PCT application nor the Clark-Lewis PCT application supplies the missing teachings of Koshiba.

For the foregoing reasons, the Section 103 rejections are improper and should be withdrawn.

Conclusion

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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